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### Pesticide Program Dialogue Committee (PPDC) PRIA Process Improvement Workgroup



April 19, 2011

## Introductions and Announcements

Marty Monell
Deputy Director
Office of Pesticide Programs
April 19, 2011

### **Statutory Provision**

"To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this Act with the goal of reducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Act of 2003 for pesticide registration actions for covered pesticide registration applications (including reduced risk applications)."

## OPP Pilot Fragrance Notification Program

SanYvette Williams-Foy, DVM CDR, USPHS Special Assistant, RMB1 Antimicrobials Division April 19, 2011

### **Objectives**

- to improve public transparency
- reduce the amount of paperwork required of the company
- decrease tracking

### Background

- 2007 Pilot
  - Updated FIL (Fragrance Ingredient List)
  - Valuable experience for registrants and fragrance suppliers
  - OPP "front end" document processing improvements

## Current Amendment Process

- Requires fragrance suppliers provide a confidential declaration of the fragrance ingredients under separate cover to the Agency
- Each fragrance formula is separately reviewed by the Inert Ingredient Assessment Branch in OPP's Registration Division (RD)
- Once reviewed, the amended CSF is accepted

## Eligibility for Participation in the Pilot Fragrance Notification Program

- Registrants must certify that all fragrance component ingredients in the newly-proposed fragrance are included on the FIL.
  - when fragrance supplier knows the fragrance but registrant does not;
  - When registrant knows the fragrance identities
- The concentration of the fragrance being added or changed must not exceed 1.0% (by weight) of the total pesticide product composition.
- Individual fragrance component ingredients > 0.1% (by weight) of the total pesticide product composition must have existing approval for use as pesticide product inert ingredients

# Eligibility for Participation in the Pilot Fragrance Notification Program (cont'd)

- Fragrance actions involving pesticide products that are insect repellents or baits are not eligible; antimicrobial aerosol products that make public health claims are not eligible.
- For non-food use pesticide products only.
- Requests for inclusion of individual fragrance ingredients not on the FIL have to be evaluated and cleared by the Agency.
- Newly proposed fragrances containing ingredients not on the FIL are ineligible for the PFNP.

# Eligibility for Participation in the Fragrance Notification Program (cont'd)

- Annual self certification is required every year (fragrance supplier and/or registrant).
- Registrant to contact the fragrance supplier to ensure that the fragrance composition is submitted to the Agency twice a year.
- Auditing of the program would be done yearly by OPP.

### Pilot Fragrance Notification Program Requirements

- A. Registrants filing a Fragrance Notification would be responsible for submitting the following:
- EPA Form 8570-1 identifying the submission as an addition of a fragrance eligible for the Pilot Fragrance Notification Program. The form is available at <a href="https://www.epa.gov/opprd001/forms"><u>www.epa.gov/opprd001/forms</u></a>.
- Fragrance Supplier Certification Letter certifying that all fragrance ingredients in the newly proposed fragrance are on the FIL.
- Confidential Statement of Formula (CSF). The form is available at <a href="https://www.epa.gov/opprd001/forms"><u>www.epa.gov/opprd001/forms</u></a>.
- B. The fragrance supplier agrees to submit certification that the composition of approved fragrances to the Inert Ingredient Branch (IRB) in the Registration Branch of the Office of Pesticide Programs

### **Process Improvement**

 Streamlining of the current process used to amend registrations when fragrance ingredients are added, removed, or modified



Questions?

#### **Updating the Label Review Manual**

Jim Roelofs
Chair, OPP Labeling
Committee
Office of Pesticide Programs
April 19, 2011

## Updating the Label Review Manual

- Up-dated all chapters by January 2010.
- Now entirely a web document accessible, links to supporting policy docs.
- Since Spring 2010, seeking outside comments
- SFIREG POM committee commenting on groups of chapters;
- Have SFIREG comments on 15 chapters so far



- Also collecting public comments via web discussion forum since September.
- Also one or two chapters at a time
   now on chapter 10 for April
- No changes to LRM text yet but may edit early chapters soon.

### **Updating LRM (continued)**

- What EPA wants from comments:
  - Editorial improvements: clearer language, better examples; more citations to supporting documents; needed up-dates.
- What EPA does not want (and generally can't do):
  - Policy discussions, requests for policy changes
  - for example, we can't just change "should" to "must".



- Workgroup screens comments for usefulness, viability – then to Label Committee;
- LRM workgroup includes OGC and OECA, as does the LC.
- Time consuming to track down rationale or origin of LRM language

#### **Label Committee**

- Continues to operate public "label consistency" Q and A website.
  - About 400 received; not all are posted.
  - LC meets weekly
  - Q is assigned to 1 person; when LC is OK with draft, answer is reviewed by all FIFRA attorneys in OGC, known as PTSLO.
- Most Q's from small registrants or consultants